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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/994,164	11/26/2001	Robert H. Keller	930068-2002.REI	9474
7590 12/09/2003				
Ronald R. Santucci				
Frommer Lawrence & Haug, LLP				
745 Fifth Avenue				
New York, NY 10151				
		EXAMINER		
		WAX, ROBERT A		
		ART UNIT		PAPER NUMBER
		1653		

DATE MAILED: 12/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/994,164	KELLER ET AL.	
	Examiner	Art Unit	
	Robert A. Wax	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 9/11/2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Reissue Applications

1. The amendment filed November 26, 2001 proposes amendments to claims that do not comply with 37 CFR 1.173(b), which sets forth the manner of making amendments in reissue applications. A supplemental paper correctly amending the reissue application is required. Since claims 30-33 are added they must be underlined.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1, 6, 22 - 24, 27, 29, 30, 32 and 33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
4. Claims 1 and 30 recite the unusual wording "N-acetylcysteine: N-acetyl-d-glucosamine vitamin C"; the colon may be a semicolon, it is unclear. More appropriate language would be, " N-acetylcysteine, N-acetyl-d-glucosamine and vitamin C". Claim 6 recites the "systematic" administration; this should read

"systemic". Claims 22-24 are not properly dependent because they recite the administration of a composition of a claim that does not claim a composition, claims 19, 2 and 21, respectively. Claim 27 recites the "probiotic of claim 1", this should more properly read, "composition of claim 26". Claim 29 does not further limit claim 4 since it recites properties of the N-acetyl-d-glucosamine and does not add any further ingredients to the composition. Claims 32 and 33 are rendered indefinite by the mere recitation of a "pharmaceutically effective amount" with no recitation of for what the amount is effective. Amendment along the lines of claims 6 *et seq.* would overcome this rejection.

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 30-33 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 30 and 31 recite proportions of ingredients in parts and support is cited as from Example 1 and Example 4. Examiner does not see support for the parts in either of the examples, or elsewhere in the specification. Claim 30 recites 2-40 parts of

N-acetylcysteine, 1-4 parts of N-acetyl-d-glucosamine and 1-4 parts of vitamin C. Claim 31 recites 1.5 parts of N-acetylcysteine, 1 part of N-acetyl-d-glucosamine and 2 parts of vitamin C. Example 1 recites 1,000-20,000 mg of N-acetylcysteine, 500-2000 mg of N-acetyl-d-glucosamine and 5,000-50,000 mg of vitamin C and Example 4 recites 1,500 mg of N-acetylcysteine, 500 mg of N-acetyl-d-glucosamine and 1,000 mg of vitamin C. It is not at all clear tat the proportions in the examples include those in the newly added claims.

7. Claims 30-33 are rejected under 35 U.S.C. 251 as being based upon new matter added to the patent for which reissue is sought. The added material which is not supported by the prior patent is as follows: See explanation above.
8. Claims 30-33 are rejected under 35 U.S.C. 251 as being an improper recapture of broadened claimed subject matter surrendered in the application for the patent upon which the present reissue is based. See *Hester Industries, Inc. v. Stein, Inc.*, 142 F.3d 1472, 46 USPQ2d 1641 (Fed. Cir. 1998); *In re Clement*, 131 F.3d 1464, 45 USPQ2d 1161 (Fed. Cir. 1997); *Ball Corp. v. United States*, 729 F.2d 1429, 1436, 221 USPQ 289, 295 (Fed. Cir. 1984). A broadening aspect is present in the reissue which was not present in the application for patent. The record of the application for the patent shows that the broadening aspect (in the reissue) relates to subject matter that applicant previously surrendered during the prosecution of the application. Accordingly, the narrow scope of the claims in the patent was not an error within the meaning of 35

U.S.C. 251, and the broader scope surrendered in the application for the patent cannot be recaptured by the filing of the present reissue application.

During prosecution of the original application applicants added the limitation "whereby the amount of Vitamin C is greater than 1000 mg" to claim 1, and argued that this is the reason why the rejection under 35 USC 102/103 should fall. See response to Office action in parent. Claim 30 lacks this limitation.

In addition, applicants argued the importance of the language, "facilitating absorption of NAC across cell membranes," (claim 1) in their response to the rejection under 35 USC 102/103. This limitation is now lacking from new claim 30.

Unlike a divisional or continuation application, applicants may not recapture subject matter (or scope of claims) surrendered in the parent. Thus, even though the same rejection under 35 USC 102/103 is not being made against claims 30-33, applicants have nevertheless surrendered claims lacking such language.

Claim Objections

9. Claims 31 and 33 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the

claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 30 recites 2 parts as the lower limit for the N-acetylcysteine but claim 31 recites only 1.5 parts.

Oath/Declaration

10. The reissue oath/declaration filed with this application is defective because it fails to meet the requirements of 37 CFR 1.63 and 37 CFR 1.175. See MPEP § 1414. The oath/declaration does not contain the "original and first inventors" statement, nor does it contain the residence post office addresses or citizenship of the inventors. A new oath/declaration is required containing all the required information and signed by both inventors; another reason the inventors need to sign a new oath or declaration is because this is a broadening reissue. Also, the declaration by the assignee is incomplete due to the blank in the first line.
11. In accordance with 37 CFR 1.175(b)(1), a supplemental reissue oath/declaration under 37 CFR 1.175(b)(1) must be received before this reissue application can be allowed.

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12. Claims 1-33 are rejected as being based upon a defective reissue oath or declaration under 35 U.S.C. 251. See 37 CFR 1.175. The nature of the defect is set forth above.

Receipt of an appropriate supplemental oath/declaration under 37 CFR 1.175(b)(1) will overcome this rejection under 35 U.S.C. 251. An example of acceptable language to be used in the supplemental oath/declaration is as follows:

"Every error in the patent which was corrected in the present reissue application, and is not covered by a prior oath/declaration submitted in this application, arose without any deceptive intention on the part of the applicant."

13. No claim is allowed. Applicant is reminded that the original patent, or a statement as to loss or inaccessibility of the original patent, must be received before this reissue application can be allowed. See 37 CFR 1.178. In addition, applicant is requested to furnish a PTO-1449 citing all the references that were cited in the parent patent.
14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Wax whose telephone number is (703) 308-4471. The examiner can normally be reached Monday - Friday from 9:00 AM to 5:30 PM.
- If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher S. F. Low, can be reached on (703) 308-2923. The fax

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phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

A handwritten signature in black ink, appearing to read 'Robert A. Wax', written in a cursive style.

Robert A. Wax
Primary Examiner
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